

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	A.G. Daifotis et al.		
Serial No.:	To Be Assigned	Case No: 20002YIBCA	Art Unit: 1617
Filed:	December 5, 2001		
For:	METHOD FOR INHIBITING BONE RESORPTION		
			Examiner: T. Criares

Assistant Commissioner for Patents
Washington, D.C. 20231

EXPRESS MAIL CERTIFICATE
DATE OF DEPOSIT December 5, 2001
EXPRESS MAIL NO. E1839873010US
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MAILED BY D. B. Crowley
DATE December 5, 2001

PRELIMINARY AMENDMENT

Sir:

The Examiner is respectfully requested to enter this Preliminary Amendment in this continuation application under 37 CFR 1.53(b).

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. Serial No. 09/388,659, filed September 2, 1999, which in turn is a continuation-in-part of PCT/US98/14796, filed July 17, 1998, which claims priority to U.S. Provisional Application Serial Number 60/053,535, filed July 23, 1997 and U.S. Provisional Application Serial Number 60/053,351, filed July 22, 1997, both now abandoned, the contents of all of the foregoing of which are hereby incorporated by reference in their entirety.

IN THE CLAIMS

Please cancel Claims 1 through 16 without prejudice and replace with the following new claims 17-29.

-- 17. A method for treating or preventing osteoporosis in a mammal, said method comprising orally administering to said mammal a pharmaceutically effective amount of ibandronate, pharmaceutically acceptable salts or esters thereof, and mixtures thereof as a unit dosage according to a continuous schedule having a dosing interval selected from the group consisting of once-weekly dosing, twice-weekly dosing, biweekly dosing, and twice-monthly dosing. --

-- 18. A method according to claim 17 wherein said mammal is a human. --

-- 19. A method according to claim 18 wherein said dosing interval is once-weekly. --

-- 20. A method according to claim 19 wherein said unit dosage comprises from about 3.5 mg to about 200 mg, on an acid active basis, of ibandronate, pharmaceutically acceptable salts or esters thereof, and mixtures thereof. --

-- 21. A method according to claim 20 wherein said unit dosage comprises about 35 mg, on an acid active basis, of ibandronate, pharmaceutically acceptable salts or esters thereof, and mixtures thereof. --

-- 22. A method according to claim 20 wherein said unit dosage comprises about 40 mg, on an acid active basis, of ibandronate, pharmaceutically acceptable salts or esters thereof, and mixtures thereof. --

-- 23. A method according to claim 20 wherein said unit dosage comprises about 45 mg, on an acid active basis, of ibandronate, pharmaceutically acceptable salts or esters thereof, and mixtures thereof. --

-- 24. A method according to claim 20 wherein said unit dosage comprises about 50 mg, on an acid active basis, of ibandronate, pharmaceutically acceptable salts or esters thereof, and mixtures thereof. --

-- 25. A method according to claim 19 wherein said unit dosage comprises about 1.5 to about 6000 $\mu\text{g/kg}$ body weight of ibandronate, pharmaceutically acceptable salts or esters thereof, and mixtures thereof. --

-- 26. A method according to claim 19 wherein said unit dosage comprises about 10 to about 2000 $\mu\text{g/kg}$ body weight of ibandronate, pharmaceutically acceptable salts or esters thereof, and mixtures thereof. --

-- 27. A method according to any one of claims 17-26 wherein said unit dosage is in the form of a tablet. --

-- 28. A method according to any one of claims 17-26 wherein said unit dosage is in the form of a capsule. --

-- 29. A method according to any one of claims 17-26 wherein said unit dosage is in the form of a liquid. --

REMARKS

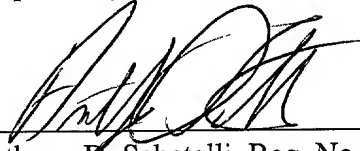
Claims 1 –16 have been cancelled without prejudice and replaced with new claims 17-29. In these new claims the method of use recites treating or preventing osteoporosis with the bisphosphonate being “ibandronate, pharmaceutically acceptable salts or esters thereof, and mixtures thereof”. Analogous claims, including claims directed to

ibandronate, had been found allowable in copending U.S. Application Serial Number 09/388,659.

Applicants earnestly request the allowance of claims 17-26 herein.

Respectfully submitted,

By



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Enclosure

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December 5, 2001

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